

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

JERRY DALMAN,)	
)	
Plaintiff,)	
)	CIVIL ACTION FILE
v.)	NO. 1:09-CV-3646-RLV
)	
C. R. BARD, INC.,)	
)	
Defendant.)	

DEFENDANT C. R. BARD, INC.'S INITIAL DISCLOSURES

C. R. Bard, Inc. ("Bard") by and through its undersigned counsel, hereby serves its Initial Disclosures in accordance with Local Rule 26.1, and states as follows:

Defendant makes these disclosures subject to and without waiver of its right to protect from disclosure any work product of its attorneys, consultants and/or other representatives, or any material protected from disclosure by the attorney-client privilege, work-product doctrine, or any other applicable privilege. Defendant also makes these disclosures subject to the right to protect from disclosure information and/or documents protected by the privacy rights and/or interests of persons who may be identified in the documents and also by federal or state statute, regulation, or other law.

In making these disclosures, Defendant does not represent that it is identifying all conceivable individuals, documents, electronically stored information, or tangible things upon which it may rely to support their defenses. Further discovery, investigation, legal research, and analysis may supply additional facts and new meaning to known facts, as well as establish new factual conclusions and legal contentions, all of which may lead to substantial changes, additions to, and variation from the disclosures. Accordingly, Defendant reserves its rights to amend these disclosures in accordance with subsequent developments, and further makes these disclosures without prejudice to its right to produce facts, witnesses, documents, electronically stored information, and other evidence omitted from these responses by oversight, inadvertence, good faith error, or mistake.

1) If the defendant is improperly identified, state defendant's correct identification and state whether defendant will accept service of an amended summons and complaint reflecting the information furnished in this disclosure response.

ANSWER: Bard is properly identified.

2) Provide the names of any parties whom defendant contends are necessary parties to this action, but who have not been named by plaintiff. If defendant contends that there is a question of misjoinder of parties, provide the reasons for defendant's contentions.

ANSWER:

Bard is unaware of any necessary parties who have not been named by the plaintiff at this time.

3) Provide a detailed factual basis for the defense or defenses and any counterclaims or cross-claims asserted by defendant in the responsive pleading.

ANSWER:

At this early stage in this litigation, Bard's knowledge of the facts of this case is limited and is derived primarily from the plaintiff's complaint. Nonetheless, Bard believes that it has strong defenses to the plaintiff's claims.

The plaintiff has filed a product liability action against Bard. The plaintiff claims that a medical device distributed by Bard was defectively designed and that its warnings were inadequate, thereby causing the plaintiff to sustain injuries.

The medical devices at issue are vaginal mesh systems. They are sold under the Avaulta® brand name, implanted surgically, and used for the treatment of pelvic organ prolapse. Pelvic organ prolapse occurs when the pelvic floor muscles become weak or damaged and can no longer support the pelvic organs. As a result, the pelvic organs can shift from their natural, intended position and/or to protrude into or outside of the vaginal canal. The Avaulta® systems functions to help restore the strength and function in the weakened tissues and pelvic floor.

The plaintiff generically claims that the Avaulta® systems were somehow defective without providing any specifics. Nonetheless, Bard has strong defenses to the plaintiff's product defect claims.

As an initial matter, the design of the Avaulta® systems is appropriate and reasonable.

In addition, the learned intermediary rule, under which manufacturers of prescription drugs and medical devices are relieved of their duty to warn the patient if the manufacturer adequately warned the prescribing physician, will bar the plaintiff's failure to warn claims. Here, Bard provided adequate information regarding the risks of its Avaulta® systems to the plaintiff's prescribing physicians. Moreover, the medical community is and was at the time of the implantation of the Avaulta® products at issue aware that transvaginal mesh products, including the ones at issue here, presented various risks. Accordingly, Bard believes that any failure to warn claim will be barred by the learned

intermediary doctrine and that the plaintiff will not be able to prove that any alleged failure to warn was the proximate cause of their injuries.

In addition, Bard believes that discovery may show that the plaintiff was at all relevant times aware of the risks associated with the Avaulta® systems and, therefore, expressly or impliedly assumed the risk of any alleged damages.

Bard also contends that plaintiff's breach of warranty claims are barred because there was no privity between the plaintiff and Bard.

Bard also believes that discovery may show that devices did not cause the plaintiff's injuries and that the plaintiff's damages may be more limited than claimed.

Bard also contends that plaintiff will not be able to provide any evidence that Bard's actions toward her showed bad faith, willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care, which would raise the presumption of conscious indifference to consequences. Bard has also raised various constitutional and other defenses related to plaintiff's alleged claim for punitive damages in this matter.

Bard further refers to the additional defenses raised in its Answer. Bard is continuing its investigation of this matter.

4) Describe in detail all statutes, codes, regulations, legal principles, standards and customs or usages, and illustrative case law which defendant contends are applicable to this action.

ANSWER: At this early stage, Bard cannot determine all of the issues that might arise during this case. Additional facts may become known which raise issues that may be governed by other statutes, codes, regulations and cases. The following list represents Bard's best effort, at this stage in the proceedings, to determine the relevant authorities:

Michigan

Renwick v. Wyeth-Ayerst Lab. Co., 1997 U.S. Dist. LEXIS 18405 (E.D.

Mich. Sept. 30, 1997)

Brown v. Drake-Willock Int'l, 209 Mich. App. 136 (Mich. Ct. App. 1995)

Marciniak v. Miles-Cutter, 874 F. Supp. 772 (W.D. Mich. 1994) *Rodger v. Ford Motor Co.*, No. 275578, 2008 Mich. App. LEXIS 2071 (Mich. App. Oct. 21, 2008)

Ghrist v. Chrysler Corp., 451 Mich. 242 (1996)

Strauch v. Raymond Corp., No. 254224, 2005 Mich. App. LEXIS 3297 (Mich. App. Dec. 29, 2005)

Wingard v. Nutro Corp., No. 262893, 2007 Mich. App. LEXIS 633 (Mich. App. March 6, 2007)

Gregory v. Cincinnati Inc., 450 Mich. 1, 11 (1995)).

Georgia

Banks v. ICI Americas, Inc., 264 Ga. 732, 737 (1994)

Blackston v. Shook and Fletcher Insulation Co., 764 F.2d 1480 (11th Cir. 1985)

Center Chemical Co. v. Parzini, 234 Ga. 868 (1975)

Geier v. American Honda Motor Company, Inc., 120 S. Ct. 1913 (2000)

Lamb v. Georgia-Pacific Corp., 194 Ga.App. 848 (1990)

Union Carbide Corp. v. Holton, 136 Ga.App. 726 (1975)

Wheat v. Sofamor, 46 F.Supp.2d 1351 (N.D. Ga. 1999)

Lashley v. Ford Motor Co., 359 F.Supp. 363 (M.D. Ga. 1972)

Johnson v. American National Red Cross, 276 Ga. 270 (2003)

Moore v. ECI Management, 246 Ga. App. 601 (2000)

Talley v. City Tank Corp., 158 Ga. App. 130 (1981)

Jones v. NordicTrack, Inc., 274 Ga. 115 (2001)

Presto v. Sandoz Pharmaceuticals Corp., 226 Ga. App. 547 (1997)

Lance v. American Edwards Laboratories, 215 Ga. App. 713 (1994)

Ellis v. C. R. Bard, Inc., 311 F.3d 1272, 1281 (2001)

O.C.G.A. § 51-1-11

O.C.G.A. § 51-11-7

O.C.G.A. § 51-12-5.1

Article I, Section I, Paragraphs I, II and V of the Georgia Constitution

Ferguson v. Trans World Airlines, Inc., 135 F. Supp. 2d 1304 (N.D. Ga. 2000 (Application of Georgia conflict of laws rules)

International Business Machines Corp. v. Kemp, 244 Ga. App. 638 (2000) (Application of lex loci delicti)

Generally Applicable Law

Restatement (Second) of Torts and Restatement (Third) of Torts: Products Liability

Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 300 et seq. and amendments thereto

Federal preemption doctrines

Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993)

General Electric v. Joiner, 522 U.S. 136 (1997)

Kumho Tire Co. v. Carmichael, 119 S.Ct. 1167 (1999)

Due Process Clauses of the Fifth and Fourteenth Amendment

BMW of N. Am. Inc. v. Gore, 517 U.S. 559, 116 S. Ct. 1589 (1996)

State Farm Mut. Auto. Ins. v. Campbell, 538 U.S. 408, 417-18, 417, 123 S. Ct. 1513, 1520 (2003).

The above list of authorities is by no means exhaustive, and Bard will supplement its response to the extent required by the Federal Rules of Civil Procedure or by the Local Rules of this Court.

5) Provide the name and, if known, the address and telephone number of each individual likely to have discoverable information that you may use to support your claims or defenses unless solely for impeachment, identifying the subjects of the information. (Attach witness list to Responses to Initial Disclosures as Attachment A).

ANSWER:

See Attachment A.

6) Provide the name of any person who may be used at trial to present evidence under Rules 702, 703, or 705 of the Federal Rules of Evidence. For all experts described in Fed.R.Civ.P. 26(a)(2)(B), provide a separate written report satisfying the provisions of the rule. (Attach expert witness list and written reports to Responses to Initial Disclosures as Attachment B.)

ANSWER:

See Attachment B.

7) Provide a copy of, or description by category and location of, all documents, data compilations, and tangible things in your possession, custody, or control that you may use to support your claims or defenses unless solely for impeachment, identifying the subjects of the information. (Attach document list and descriptions to Responses to Initial Disclosures as Attachment C.)

ANSWER:

See Attachment C.

8) In the space provided below, provide a computation of any category of damages claimed by you. In addition, include a copy of, or describe by category and location of, the documents or other evidentiary material, not privileged or protected from disclosure on which such computation is based, including materials bearing on the nature and extent of injuries suffered, making such documents or evidentiary material available for inspection and copying under Fed.R.Civ.P.34. (Attach any copies and descriptions to Responses to Initial Disclosures as Attachment D).

ANSWER:

Not applicable at present. Bard reserves the right to amend this response as discovery progresses.

9) If defendant contends that some other person or legal entity is, in whole or in part liable to the plaintiff or defendant in this matter, state the full name, address, and telephone number of such person or entity and describe in detail the basis of such liability.

ANSWER:

Not applicable at present.

10) Attach for inspection and copying as under Fed.R.Civ.P. 34 any insurance agreement under which any person carrying on an insurance business may be liable to satisfy part or all of a judgment which may be entered in this action or to indemnify or reimburse for payments to satisfy the

judgment. (Attach copy of insurance agreement to Responses to Initial Disclosures as Attachment E.)

ANSWER:

Bard is self-insured for an amount more than sufficient to cover any conceivable verdict in this case. Although such insurance should not be implicated by this claim, Bard also carries ample excess insurance.

Respectfully submitted this 10th day of February, 2010.

/s/ Richard B. North, Jr.

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COUNSEL FOR DEFENDANT C. R. BARD, INC.

DEFENDANT'S ATTACHMENT "A"

At this time, Bard does not have a sufficient basis upon which to identify all individuals who have information that it may use to support its claims or defenses. Subject to the foregoing, the following individuals are likely to have discoverable factual information that Bard may use to support its claims or defenses:

1. Plaintiff
2. Robert Orr, III
Director, Advanced Surgical Concept
C. R. Bard, Inc.
c/o Nelson, Mullins, Riley & Scarborough LLP
May have knowledge regarding the development, testing, design, and safety of the Avaulta® line of products
3. John Knorpp
Director, Regulatory Affairs
C. R. Bard, Inc.
c/o Nelson, Mullins, Riley & Scarborough LLP
May have knowledge regarding the regulatory history for the Avaulta® line of products
4. The plaintiff's health care providers or professionals
5. Any and all individuals with knowledge of the plaintiff's health history
6. Any and all individuals designated as witnesses by the plaintiff
7. Any individuals identified by other parties or in documents produced by other parties, in initial disclosures, in other discovery responses, or during depositions

Bard reserves the right to supplement and/or amend this list during or at the close of discovery in this action and to call witnesses not listed in its initial disclosures or

on court-ordered witness lists to the extent those witnesses will be called solely for impeachment. The names listed above should not be construed as an admission that any or all of the facts known to the individuals listed are legally relevant or admissible. Bard reserves all rights to raise appropriate legal challenges to the admissibility of their testimony.

DEFENDANT'S ATTACHMENT "B"

Bard has not yet made a decision as to whom it may call as an expert witness at trial at this time.

DEFENDANT'S ATTACHMENT "C"

Based upon the allegations of the Complaint, Defendant submits the following description by category of documents, electronically stored information, and tangible things that are in its possession, custody, or control and that it may use to support its claims or defenses:

1. The Instructions for Use (IFU) for the subject products
2. The Device History Records for the lots which included the subject products
3. 510(k) submissions for the subject products
4. Representative marketing material for the subject products
5. The Complaint file(s) for the subject incident
6. Design history file/documents
7. The plaintiff's medical and pharmacy records obtained from third-parties and/or the plaintiff
8. Documents and information obtained from any third parties during discovery
9. Any documents listed by the plaintiff
10. Any documents produced during the discovery of this case

Defendant reserves the right to supplement this list to include any other documents identified during the course of discovery that contain information that may be used by it to support its defenses in this action.

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ATLANTA DIVISION

JERRY DALMAN,)	
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Plaintiff,)	
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v.)	NO. 1:09-CV-3646-RLV
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C. R. BARD, INC.,)	
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Defendant.)	

CERTIFICATE OF SERVICE

I hereby certify that on this 10th day of February, 2010 I electronically filed the foregoing **DEFENDANT C. R. BARD, INC.'S INITIAL DISCLOSURES** with the Clerk of Court using the CM/ECF system which will automatically send email notification of such filing to the following attorneys of record:

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Henry G. Garrard, III
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/s/ Richard B. North, Jr.
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